

REMARKS

The Examiner rejected claims 1-32 under 35 U. S. C. § 102. The Examiner relied upon Brown U. S. Patent 5,307,263 (hereinafter Brown) to support this rejection.

For claims 1 to 5, the Examiner calls Applicants' attention specifically to Brown's i) Fig. 1 and Col. 7, lines 28-47 to teach a hand held microprocessor based unit 12 for sensing blood glucose level; ii) Col. 8, lines 14-45 to teach a set of program instruction; iii) Col. 11, lines 17-38 to teach a modem connects a first port to a second port for transmit and receive instruction; and iv) Col. 14, line 9 to Col. 15, line 5 to teach message or instruction display.

Claim 1 has been amended to recite that

“connecting said first port [of the configuring computer] directly to said second port [of the hand-held instrument for determining the concentration of a medically significant component of a body fluid or a control], transmitting [said] one of instructions and data to configure said instrument from said first port directly to said second port, receiving said one of instructions and data directly from said first port at said second port, and configuring said instrument according to said one of instructions and data transmitted from said first port and received at said second port.”

Brown does not disclose or suggest connecting a first port of a configuring computer directly to a second port of a hand-held instrument for determining the concentration of a medically significant component of a body fluid or a control, transmitting instructions or data to configure the instrument from the first port directly to the second port, receiving the instructions or data directly from the first port at the second port, and configuring the instrument according to the instructions or data transmitted from the first port and received at the second port.

Brown discloses that

“in the currently preferred embodiments of the invention, blood glucose monitor 16 operates in conjunction with data management unit 10 and handheld microprocessor unit 12 to: (a) perform a test or calibration sequence in which test (sic-- tests) are performed to confirm that the system is operating properly; and, (b) perform the blood glucose test sequence in which blood glucose meter 16 senses the user's blood glucose level. Suitable calibration procedures for blood glucose monitors are known in the art. For example, blood glucose monitors often are supplied with a ‘code strip,’ that is inserted in the monitor and results in a predetermined value being displayed and stored in memory at the conclusion of the code strip calibration procedure. When such a code strip calibration

procedure is used in the practice of the invention, the procedure is selected from one of the system menus. For example, if the system main menu includes a 'monitor' menu item, a submenu displaying system calibration options and an option for initiating the blood glucose test may be displayed when the monitor menu item is selected. When a code strip option is available and selected, a sequence of instructions is generated and displayed by display screen 28 of handheld microprocessor unit 12 to prompt the user to insert the code strip and perform all other required operations. At the conclusion of the code strip calibration sequence, display unit 28 of handheld microprocessor unit 12 displays a message indicating whether or not the calibration procedure has been successfully completed. For example, FIG. 4 illustrates a screen display that informs the system user that the calibration procedure was not successful and that the code strip should be inserted again (i.e., the calibration procedure is to be repeated). As is indicated in FIG. 4, display screens that indicate a potential malfunction of the system include a prominent message such as the 'Attention' notation included in the screen display of FIG. 4.

"As previously indicated, the blood glucose test sequence that is employed in the currently preferred embodiment of the invention is of the type in which a test strip is inserted in a receptacle that is formed in the blood glucose monitor. A drop of the user's blood is then applied to the test strip and a blood glucose sensing sequence is initiated. When the blood glucose sensing sequence is complete, the user's blood glucose level is displayed.

"In the practice of the invention, program instructions stored in data management unit 10 (e.g., system ROM 90 of FIG. 3) and program instructions stored in program cartridge 42 of handheld microprocessor unit 12 cause the system to display step-by-step monitoring instructions to the system user and, in addition, preferably result in display of diagnostic messages if the test sequence does not proceed in a normal fashion. Although currently available self-contained microprocessor-based blood glucose monitors also display test instruction and diagnostic messages, the invention provides greater message capacity and allows multi-line instructions and diagnostic messages that are displayed in easily understood language rather than cryptic error codes and abbreviated phraseology that is displayed one line or less at a time. For example, as is shown in FIG. 5, the complete results of a blood glucose test (date, time of day, and blood glucose level in milligrams per deciliter) can be concurrently displayed by display screen 28 of handheld microprocessor unit 12 along with an instruction to remove the test strip from blood glucose monitor 16. As previously mentioned, when the blood glucose test is complete, the time and date tagged blood glucose test result is stored in the

memory circuits of data management unit 10 (e.g., stored in EEPROM 94 of FIG. 3).”

Brown, col. 17, line 14-col. 18, line 18.

Brown further discloses that

“The screen display shown in FIG. 8 is representative of statistical data that can be determined by the system of FIG. 1 (using conventional computation techniques) and displayed in alphanumeric format. As previously mentioned, such statistical data and information in various other textual and graphic formats can be provided to a healthcare professional (60 in FIG. 2) in the form of a standardized report 56 (FIG. 1) that is sent by clearinghouse 54 to facsimile machine 55. In the exemplary screen display of FIG. 8, statistical data for blood glucose levels over a period of time (e.g., one week) or, alternatively, for a specified number of monitoring tests is provided. In the exemplary display of FIG. 8, the system (data management unit 10 or clearinghouse 54) also calculates and displays (or prints) the average blood glucose level and the standard deviation. Displayed also is the number of blood glucose test results that were analyzed to obtain the average and the standard deviation; the number of test results under a predetermined level (50 milligrams per deciliter in FIG. 8); and the number of blood glucose tests that were conducted while the user was experiencing hypoglycemic symptoms. As previously noted, in the preferred embodiments of the invention, a screen display that is generated during the blood glucose monitoring sequence allows the user to identify the blood sample being tested as one taken while experiencing hyperglycemic or hypoglycemic symptoms and, in addition, allows the user to specify other relevant information such as food intake and medication information.”

Brown, col. 19, lines 8-37.

Brown discloses that

“[s]ome currently available blood glucose monitoring systems provide a data port that can be interconnected with and transfer data to a personal computer (e.g., via an RS-232 connection). With such a system and a suitable programmed computer, the user can generate and display trend information or other data that may be useful in administering his or her treatment plan. Moreover, in such systems, data also can be transferred from the blood glucose monitoring system to a healthcare professional's computer either directly or remotely by telephone if both the blood glucose monitoring system (or computer) to which the data has been downloaded and the healthcare professional's computer are equipped with modems. Although such a data transfer provision allows a healthcare professional to analyze blood glucose data collected by a diabetic, this aspect of currently available blood glucose monitoring systems

has not found widespread application. First, the downloading and subsequent analysis feature can only be used by system users that have ready access to a computer that is programmed with appropriate software and, in addition, have both the knowledge required to use the software (and the inclination to do so). This same problem exists with respect to data transfer to (and subsequent analysis by) a healthcare professional. Moreover, various manufacturers of systems that currently provide a data transfer feature do not use the same data format. Therefore, if a healthcare professional wishes to analyze data supplied by a number of different blood glucose monitoring systems, he or she must possess software for each of the systems and must learn to conduct the desired analyses with each software system.”

Brown, col. 3, line 49-col. 4, line 12.

Brown discloses that

“[Brown’s] invention provides a new and useful system for healthcare maintenance in which the invention either serves as a peripheral device to (or incorporates) a small handheld microprocessor-based unit of the type that includes a display screen, buttons or keys that allow a user to control the operation of the device and a program cartridge or other arrangement that can be inserted in the device to adapt the device to a particular application or function. The invention in effect converts the handheld microprocessor device into a healthcare monitoring system that has significant advantages over systems such as the currently available blood glucose monitoring systems. To perform this conversion, the invention includes a microprocessor-based healthcare data management unit, a program cartridge and a monitoring unit. When inserted in the handheld microprocessor unit, the program cartridge provides the software necessary (program instructions) to program the handheld microprocessor unit for operation with the microprocessor-based data management unit. Signal communication between the data management unit and the handheld microprocessor unit is established by an interface cable. A second interface cable can be used to establish signal communication between the data management unit and the monitoring unit or, alternatively, the monitoring unit can be constructed as a plug-in unit having an electrical connector that mates with a connector mounted within a region that is configured for receiving the monitoring unit.

“In operation, the control buttons or keys of the handheld microprocessor-based unit are used to select the operating mode for both the data management unit and the handheld microprocessor-based unit. In response to signals generated by the control buttons or keys, the data management unit generates signals that are coupled to the handheld microprocessor unit

and, under control of the program instructions contained in the program cartridge, establish an appropriate screen display on the handheld microprocessor-based unit display. In selecting system operating mode and other operations, the control buttons are used to position a cursor or other indicator in a manner that allows the system user to easily select a desired operating mode or function and provide any other required operator input. In the disclosed detailed embodiment of the invention several modes of operation are made available.”

Brown, col. 4, line 66-col. 5, line 43.

Brown discloses that

“[a] microprocessor-based health monitoring system that is configured in accordance with the invention provides additional advantages for both the user and a healthcare professional. In accordance with one aspect of the invention, standardized reports are provided to a physician or other healthcare provider by means of facsimile transmission. To accomplish this, the data management unit of the currently preferred embodiments of the invention include a modem which allows test results and other data stored in system memory to be transmitted to a remote clearinghouse via a telephone connection. Data processing arrangements included in the clearinghouse perform any required additional data processing; format the standardized reports; and, transmit the reports to the facsimile machine of the appropriate healthcare professional.

“The clearinghouse also can fill an additional communication need, allowing information such as changes in medication dosage or other information such as modification in the user's monitoring schedule to be electronically sent to a system user. In arrangements that incorporate this particular aspect of the invention, information can be sent to the user via a telephone connection and the data management unit modem when a specific inquiry is initiated by the user, or when the user establishes a telephone connection with the clearinghouse for other purposes such as providing data for standardized reports.”

Brown, col. 6, lines 5-33.

With continued reference to Brown's Fig. 1, Brown further provides that

“data management unit 10 of the currently preferred embodiments of the invention includes a data port 44 that allows communication between data management unit 10 and a personal computer 48 (or other programmable data processor). In the currently preferred embodiments of the invention, data port 44 is an RS-232 connection that allows serial data communication between data management unit 10 and personal computer 48. In the practice of the invention, personal computer 48 can be used to supplement data management unit 10 by, for example, performing more complex analyses of

blood glucose and other data that has been supplied to and stored in the memory circuits of data management unit 10. With respect to embodiments of the invention configured for use by a child, personal computer 48 can be used by a parent or guardian to review and analyze the child's progress and to produce printed records for subsequent review by a healthcare professional. Alternatively, personal computer 48 can be used to supply data to data management unit 10 that is not conveniently supplied by using handheld microprocessor switches 30, 32, 34, 36 and 38 as an operator interface to the system shown in FIG. 1. For example, some embodiments of the invention may employ a substantial amount of alphanumeric information that must be entered by the system user. Although it is possible to enter such data by using switches 30, 32, 34, 36 and 38 in conjunction with menus and selection screens displayed on display screen 28 of FIG. 1, it may be more advantageous to use a device such as personal computer 48 for entry of such data. However, if personal computer 48 is used in this manner, some trade-off of system features may be required because data management unit 10 must be temporarily interconnected with personal computer 48 during these operations. That is, some loss of system mobility might result because a suitably programmed personal computer would be needed at each location at which data entry or analysis is to occur.

“As is indicated in FIG. 1, data management unit 10 of the currently preferred embodiments of the invention also includes a modem that allows data communication between data management unit 10 and a remote computing facility identified in FIG. 1 as clearinghouse 54 via a conventional telephone line (indicated by reference numeral 50 in FIG. 1) and a modem 52 that interconnects clearinghouse 54 and telephone line 50. As shall be described in more detail, clearinghouse computing facility 54 facilitates communication between a user of the system shown in FIG. 1 and his or her healthcare professional and can provide additional services such as updating system software. As is indicated by facsimile machine 55 of FIG. 1, a primary function of clearinghouse 54 is providing the healthcare professional with standardized reports 56, which indicate both the current condition and condition trends of the system user. Although a single facsimile machine 55 is shown in FIG. 1, it will be recognized that numerous healthcare professionals (and hence facsimile machine 55) can be connected in signal communication with a clearinghouse 54.”

Brown, col. 10, line 47-col. 11, line 39.

Brown further provides,

“Referring first to FIG. 2, clearinghouse 54 receives data from a plurality of self-care microprocessor-based healthcare

systems of the type shown in FIG. 1, with the individual self-care health monitoring systems being indicated in FIG. 2 by reference numeral 58. Preferably, the data supplied to clearinghouse 54 by each individual self-care health monitoring system 58 consists of 'raw data,' i.e., test results and related data that was stored in memory circuits of data management unit 10, without further processing by data management unit 10. For example, with respect to the arrangement shown in FIG. 1, blood glucose test results and associated data such as food intake information, medication dosage and other such conditions are transmitted to clearinghouse 54 and stored with a digitally encoded signal that identifies both the source of the information (i.e., the system user or patient) and those having access to the stored information (i.e., the system user's doctor or other healthcare professional).

"As shall be recognized upon understanding the manner in which it operates, clearinghouse 54 can be considered to be a central server for the various system users (58 in FIG. 2) and each healthcare professional 60. In that regard, clearinghouse 54 includes conventionally arranged and interconnected digital processing equipment (represented in FIG. 2 by digital signal processor 57) which receives digitally encoded information from a user 58 or healthcare professional 60; processes the information as required; stores the information (processed or unprocessed) in memory if necessary; and, transmits the information to an intended recipient (i.e., user 58 or healthcare professional 60)."

Brown, col. 11, line 65-col. 12, line 28.

Brown further provides that

"The arrangement of FIG. 2 also allows the healthcare professional to send messages and/or instructions to each patient via computer 62, telephone line 64, and clearinghouse 54. In particular, clearinghouse 54 can be programmed to generate a menu that is displayed by computer 62 and allows the healthcare professional to select a mode of operation in which information is to be sent to clearinghouse 54 for subsequent transmission to a user of the system described relative to FIG. 1. This same menu (or related submenus) can be used by the healthcare professional to select one or more modes of operation of the above-described type in which either unmodified patient data or the results of data that has been analyzed by clearinghouse 54 is provided to the healthcare provider via computer 62 and/or facsimile machine 55.

"In the currently contemplated arrangements, operation of the arrangement of FIG. 2 to provide the user of the invention with messages or instructions such as changes in medication or other aspects of the healthcare program is similar to the operation that allows the healthcare professional to access data sent by a

patient, i.e., transmitted to clearinghouse 54 by a data management unit 10 of FIG. 1. The process differs in that the healthcare professional enters the desired message or instruction via the keyboard or other interface unit of computer 62. Once the data is entered and transmitted to clearinghouse 54, it is stored for subsequent transmission to the user for whom the information or instruction is intended.”

Brown, col. 13, lines 17-46.

In none of this extensive, quoted explanation from Brown is there any disclosure or suggestion of connecting a first port of a configuring computer directly to a second port of a hand-held instrument for determining the concentration of a medically significant component of a body fluid or a control, transmitting instructions or data to configure the instrument from the first port directly to the second port, receiving the instructions or data directly from the first port at the second port, and configuring the instrument according to the instructions or data transmitted from the first port and received at the second port.

At least for the above reasons, the 35 U. S. C. § 102 rejection of claims 1-32 based upon Brown is thus overcome. Accordingly, Applicants submit that claims 1-32 are in condition for further favorable consideration, culminating in allowance. Such action is respectfully requested.

Applicants hereby petition for a two month extension of the term for response to the March 3, 2005 official action to and including August 3, 2005. The Commissioner is hereby authorized to charge the fee for this extension of time, as well as any other fees which may be due to constitute this a timely response to the March 3, 2005 official action, to Applicants’ undersigned counsel’s deposit account 10-0435 with reference to file number 5727-65998. A duplicate copy of this authorization is enclosed for that purpose.

Respectfully submitted,



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